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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,533	07/10/2001	Chong Jin Oon	U 013108-9	8503

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT PAPER NUMBER

1648

DATE MAILED: 05/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/719,533	OON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above claim(s) 15-24 and 27-74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-8,10-14,25 and 26 is/are rejected.
- 7) ☒ Claim(s) 3, 4, and 9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input checked="" type="checkbox"/> Other: <u>See Continuation Sheet.</u>           |

Continuation of Attachment(s) 6). Other: Raw Sequence Listing Error Report.

## DETAILED ACTION

### *Status of the Claims*

1. Currently claims 1-74 are pending in the application. In the prior action, mailed on August 10, 2004, claims 1, 2, 5-8, 10-14, 25, and 26 were rejected; claims 3 and 9 were objected to, and claims 15-24 and 27-74 were withdrawn as to non-elected inventions. In the Amendments of February and April 2005, the Applicant amended claims 4, 25, and 26.
2. Claims 1-14, 25, and 26 are pending and under consideration.

### *Sequence Listing*

3. **(New Objection- Necessitated by Amendment)** The Computer readable form (CRF) of the amendment sequence listing is objected to for the reasons indicated in the attached Raw Sequence Listing Error Report.

Appropriate correction is required.

4. **(New Objection- Necessitated by Amendment)** The sequence listing is objected to for identifying SEQ ID NO: 6 as having 35, rather than 36, amino acid residues.

Appropriate correction is required.

### *Specification*

5. **(Prior Objection-Withdrawn)** The disclosure was objected to because of the following informalities: the application indicates that the polypeptide of SEQ ID NO: 3 is encoded by the nucleic acid of SEQ ID NO: 1. A comparison of SEQ ID NO: 1 (and in particular bases 287-292

Art Unit: 1648

of the sequence) with SEQ ID NO: 3 (esp. residues 219 and 220) shows that the amino residues 219 and 220 placed in the order proline-threonine should, according to the coding sequence of SEQ ID NO: 1, read threonine-proline. In view of the amendment of the sequence listing to read in this manner, the objection is withdrawn.

6. **(Prior Objection-Withdrawn)** The specification was objected to because the description of the Figures provided on pages 6-8 of the application indicate that there are 13 Figures in the Application. It was indicated in the prior action that only 2 pages of drawings are present in the application; a first apparently corresponding to described Figure 1, and a second that does not appear to correspond to any of the described figures. The Applicant has amended the description of Figure 2 to match the second figure presented. The Applicant also notes the amendment to the specification of December 13, 2002, which amended the specification to refer only to the two present figures. The objection is therefore withdrawn.

7. **(Prior Objection-Maintained)** The disclosure was objected to because of the following informalities: in several instances (pages 4, 11, 18, 25, and 32) the text of the specification is faded such that it is not legible. In an attempt to correct this error, the Applicant has submitted replacement pages of the specification. However, there is no provision in the Patent Rules for such a form of correction. The Applicant is required to submit a correction of the specification in compliance with 37 CFR 1.121 and 1.125. In specific, the Applicant is requested to provide either the appropriate substitute sections, or a substitute specification.

Appropriate correction is required.

***Claim Objections***

8. **(Prior Objection- Maintained)** Claim 4 was objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. This claim purports to further limit the invention of claim 3 to embodiments wherein the isolated nucleic acid of SEQ ID NO: 3 comprises the sequence AGA at positions 587-89. The “further limitation” of claim 4 is in fact an inherent property of SEQ ID NO: 1. Because claim 4 still depends from claim 3 in the amendment of April 2005, the objection is maintained.

***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. **(Prior Rejection-Maintained)** Claims 25 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims were rejected as indefinite for three reasons.

First, it was unclear what is meant by a “unique sequence of nucleotides.” In view of the cancellation of this language from the claims (in the amendment of February 2005) the rejection is withdrawn on this basis.

With respect to the second and third grounds of rejection, the Applicant asserts that the rejection for indefiniteness is improper, and should be applied as an enablement rejection. This

Art Unit: 1648

argument is not found persuasive. While the claims may also lack enablement, because in each of the second and third grounds of rejection, the claims require to mutually exclusive functional activities of the claimed nucleic acids, it is also unclear what is being claimed. Thus, as it is not clear what is being claimed, the rejection is proper and is maintained.

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. **(Prior Rejection-Maintained)** Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. This claim is rejected because the claim depends for enablement on a **Deposit without a promise for availability**. The Applicant presents no argument that the rejection is improper, but asks that the rejection be held in abeyance. The rejection is not held in abeyance. As no arguments or other response to the rejection have been provided, and as the rejection is still found proper, the rejection is maintained.

***Claim Rejections - 35 USC § 102***

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1648

14. **(Prior Rejection-Maintained)** Claims 2, 5, 8, 10, 11, 25, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Ho et al. (Clin Diagn Lab Immunol 2(6): 760-62). The Applicant traverses this rejection by asserting that the Ho reference is not a printed publication under 35 U.S.C. 102(b). The basis for this assertion appears to be that the Ho reference was not acknowledged by those in the art prior to the filing date of present application, and that certain persons of skill in the art were not aware of the reference. Nonetheless, the fact that persons of skill in the art were not aware of the reference is not evidence that demonstrates that the reference was not a printed publication under 35 USC 102(b). A reference is proven to be a "printed publication" "upon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it." See, MPEP 2128 (quoting the CCPA decision of *In re Wyer*, 210 USPQ 790 (1981)). Further, the Federal Circuit has determined that a single doctoral thesis indexed and shelved in a library is sufficiently accessible to the public to constitute prior art. *In re Hall*, 228 U.S.P.Q. 453 (1986). In this case, evidence has been presented that the reference in question was disseminated to the public. I.e., the name of the publication, and the volume, page number, and date of publication have been provided. The Applicant has presented evidence that those in the art were unaware of the reference, but none that the reference has not been published in fact. The argument in traversal is therefore not found persuasive, and the rejection is maintained.

***Claim Rejections - 35 USC § 103***



Art Unit: 1648

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. **(Prior Rejection-Maintained)** Claims 2, 5, 8, 10-14, 25, and 26 rejected under 35

U.S.C. 103(a) as being unpatentable over Ho et al. (supra) in view of WO 91/14703. The

Applicant traverses this rejection on the same grounds as argued with respect to the anticipation rejection over Ho above. As this argument is not found persuasive, and as no other arguments have been presented, the rejection is maintained.

17. **(Prior Rejection-Maintained)** Claims 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ho in view of WO 91/14703 as applied above, and further in view of U.S.

Patent 5,830,759. The Applicant traverses this rejection on the same grounds as argued with respect to the anticipation rejection over Ho above. As this argument is not found persuasive, and as no other arguments have been presented, the rejection is maintained.

### ***Conclusion***

18. No claims are allowed. Claims 3 and 9 are objected for depending on rejected claims.

19. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

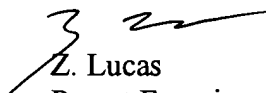
Art Unit: 1648

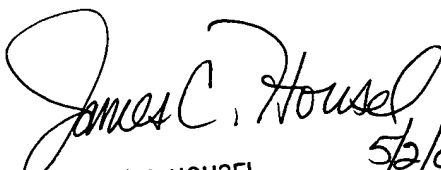
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Z. Lucas  
Patent Examiner

  
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5/2/05